

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Viswanathan SRINIVASAN et al.	Confirmation No. 4898
			Group Art Unit: 1615
Appl. No:	:	10/798,884	
			Examiner: Woodward, Michael P.
Filed	:	March 12, 2004	
For	:	DOSAGE FORM CONTAINING A MORPHINE DERIVATIVE AND ANOTHER DRUG	

ELECTION WITH TRAVERSE

Commissioner for Patents
U.S. Patent and Trademark Office
Customer Service Window, Mail Stop Amendment
Randolph Building
401 Dulany Street
Alexandria, VA 22314

Sir:

This is in response to the requirement for restriction under 35 U.S.C. § 121 mailed from the U.S. Patent and Trademark Office on April 6, 2007. Inasmuch as the one-month shortened statutory period for reply is set in the Office Action to expire on May 7, 2007 (May 6 being a Sunday), this response is being filed by the initial due date for response. However, if any extension of time is necessary, this is an express request for any necessary extension of time and authorization to charge any required extension of time fee or any other fees which may be required to preserve the pendency of the present application to Deposit Account No. 19-0089.

RESTRICTION REQUIREMENT

The Examiner has required restriction under 35 U.S.C. 121 and 372 to one of the following inventions:

- I. Claims 1-52, 72-77, 78-98, drawn to a pharmaceutical dosage form, bilayered and multilayered tablets classified in class 424, subclass 400.
- II. Claims 53-63, drawn to a liquid dosage form, classified in class 424, subclass 400.
- III. Claims 64-69, drawn to a method of alleviating a condition, classified in class 424, subclass 400.
- IV. Claims 70-71, drawn to a process of making a pharmaceutical dosage form (tablets), classified in class 424, subclass 400.

ELECTION

In order to be responsive to the requirement for restriction, Applicants elect, with traverse, the invention set forth in Group I, claims 1-52, 72-77, and 78-98.

TRAVERSE

Applicants respectfully submit that a restriction requirement is inappropriate in this case. Even if one were to assume, *arguendo*, that the inventions of Groups I to IV are distinct, the requirement for restriction should be withdrawn because there is no serious burden.

In MPEP Chapter 800, the Office sets forth its policy by which examiners are guided in requiring restriction under 35 U.S.C. § 121. Section 803 states that “[i]f the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to distinct or independent inventions.”

Applicants note that the inventions of all of the four groups identified in the Restriction Requirement relate to a specific combination of at least two drugs, wherein the plasma

concentration within the therapeutic range of one drug is coextensive for a defined period over the plasma concentration within the therapeutic range of the at least one second drug.

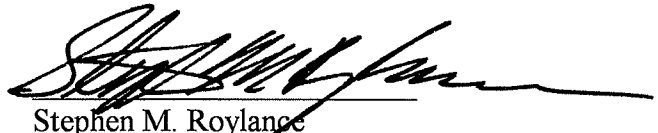
Accordingly, as a practical matter, the searches for inventions I to IV should significantly overlap, if not be substantially coextensive. For example, a search for the invention of Group I should cover many (if not almost all) of the areas that are also relevant for the inventions of Groups II to IV. Thus, the search burden would not be serious.

For the above reasons alone, the Restriction Requirement should be withdrawn, which action is respectfully requested.

The Examiner is reminded of the rejoinder practice set forth in MPEP § 821.04, i.e., if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend or otherwise include all of the limitations of the allowable product claim will be rejoined.

Should there be any questions, the Examiner is respectfully invited to contact the undersigned at the telephone number below.

Respectfully submitted,
Viswanathan SRINIVASAN et al.



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May 2, 2007
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